MAR - 9 2004

Medtronic Sofamor Danek
ARROWHEAD™ Spinal System
510(k) Summary – K032560
November 2003

Submitter:
Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

Contact Person:
Richard Treharne
Sr. Vice President Regulatory Affairs

Trade Name:
ARROWHEAD™ Spinal System

Classification:
Pedicle Screw Spinal System, Class III
21 CFR 888.3070
Product Code: MNH, MNI, NKB

Predicate Device(s):
The ARROWHEAD™ Spinal System is substantially equivalent to the CD HORIZON® Spinal System, the EQUATION™ Fixation System and the TSRH® Spinal System.

Device Description:
The ARROWHEAD™ Spinal System consists of a variety of shapes and sizes of screws and 4.5mm rods. The implant components can be rigidly locked in a variety of configurations, with each construct being tailor-made for the individual case. The implants are made of titanium alloy and commercially pure titanium. Stainless steel and titanium implant components must not be used together in a construct. The ARROWHEAD™ Spinal System components can be used with CD HORIZON® ECLIPSE® 4.5mm Rods and TSRH® 3D Short Post Screws.

Intended Use:
The ARROWHEAD™ Spinal System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Functionality & Safety Testing:
Mechanical testing was performed on the ARROWHEAD™ Spinal System. The test results were provided in this submission.

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Conclusion: The ARROWHEAD Spinal System is substantially equivalent to the EQUATION™ Fixation System, the TSRH® Spinal System and to the CD HORIZON® Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Richard W. Treharne, Ph.D.
Senior Vice President, Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K032560
Trade/Device Name: ARROWHEAD™ Spinal System
Regulatory Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH
Dated: February 25, 2004
Received: February 27, 2004

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

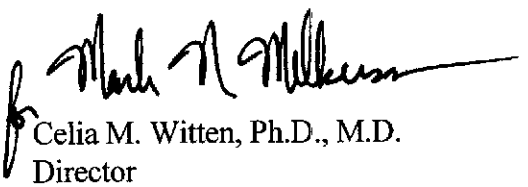
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K032560

Device Name: ARROWHEAD™ Spinal System

Indications For Use:

The ARROWHEAD™ Spinal System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032560